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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/913,325

08/10/2001

Martin Gleave

UBC.P-020

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07/19/2004

OPPEDAHL AND LARSON LLP

P O BOX 5068

DILLON, CO 80435-5068

EXAMINER

LACOURCIERE, KAREN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--------------------------|------------------------|---------------------|--|
| Interview Summary | Application No. | Applicant(s) | |
| | 09/913,325 | GLEAVE ET AL. | |
| | Examiner | Art Unit | |
| | Karen A. Lacourciere | 1635 | |

All participants (applicant, applicant's representative, PTO personnel):

- (1) Karen A. Lacourciere. (3) ____.
- (2) Marina Larson. (4) ____.

Date of Interview: 14 January 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: ____.

Claim(s) discussed: All pending claims.


Identification of prior art discussed: none.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant confirmed the election of Group IV and the Examiner agreed to rejoin Groups IV-VI. Claims 18-23 and SEQ ID NO:4, 5 and 12 will be examined on the merits.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.


KAREN A. LACOURCIERE, Ph.D.
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

SUPPLEMENTAL DETAILED ACTION

In response to Applicant's Remarks Submitted 10-30-2003, which indicated that claims were missing in the restriction requirement, a phone call was placed to Applicant to confirm the election of Group IV and SEQ ID NO:4. Applicant could not provide a confirmation within the time frame required for the Examiner to respond to the election, so a new restriction was set forth, as described below. Inadvertently, a copy of the prior Restriction requirement, mailed 10-03-2003, was mailed on 01-14-2004, instead of the updated requirement. This Supplemental Action is being sent to clarify the record and provide the proper restriction.

Additionally, Applicant contacted the Examiner by telephone on January 20, 2004, to provide a telephonic election, as outlined in the attached Interview Summary. During the interview, Applicant confirmed the election of Group IV and the Examiner agreed to rejoin Group IV-VI, in consideration of the PCT search and the fact that this case is part of a series of three cases, which include claims to SEQ ID NO: 4, 5 and 12.

Applicant's telephonic election is sufficient to fulfill their requirement to respond to this Office action and the Office action mailed 01-14-2004.

The restriction set forth in the prior office action, mailed 10-03-2003, is hereby withdrawn and a new restriction is set forth herein. This new restriction is set forth to address claims 24-34, which were not included as part of the original restriction because of improper indexing in the electronic file. The Examiner apologizes for any inconvenience to Applicant.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6-9, 12-17, 24, 25, 26, 29 and 30, drawn to a method of delaying progression of prostatic tumor cells to an androgen-independent state using an antisense of SEQ ID NO:4.

Group II, claim(s) 1, 2, 4, 6-8, 10, 12-17, 24, 25, 27, 31 and 32, drawn to a method of delaying progression of prostatic tumor cells to an androgen-independent state using an antisense of SEQ ID NO:5.

Group III, claim(s) 1, 2, 5, 6-8, 11, 12-17, 24, 25, 28, 33 and 34, drawn to a method of delaying progression of prostatic tumor cells to an androgen-independent state using an antisense of SEQ ID NO:12.

Group IV, claim(s) 18-23, drawn to a method of enhancing the chemo- or radiation sensitivity of cancer cells using SEQ ID NO:4.

Group V, claim(s) 18-23, drawn to a method of enhancing the chemo- or radiation sensitivity of cancer cells using SEQ ID NO:5.

Group VI, claim(s) 18-23, drawn to a method of enhancing the chemo- or radiation sensitivity of cancer cells using SEQ ID NO:12.

Art Unit: 1635

The inventions listed as Groups I and II and III and IV and V and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This international searching authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons indicated below:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed antisense sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The inventions of each of Groups I and II and III lack unity of invention because each of the inventions utilizes a different antisense sequence, namely SEQ ID NO:4, 5 and 12.

The inventions of each of Groups IV and V and VI lack unity of invention because each of the inventions utilizes a different antisense sequence, namely SEQ ID NO:4, 5 and 12.

The instant antisense sequences, SEQ ID NO: 4 and 5 and 12 are considered to be each separate inventions for the following reasons:

The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. Although the sequence target and modulate expression of the same gene, each antisense sequence behaves in a different way in the context of the claimed invention. Each sequence targets a different and specific region of TRPM-2 and each sequence modifies the expression of the gene to a varying degree. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved.

Further, although the sequence target the same gene, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the antisense sequences is lacking and each antisense sequence claimed is considered to constitute a special technical feature.

The inventions of each of Groups I and II and III lack unity of invention with each of the invention of Groups IV and V and VI because they lack a common corresponding technical feature, for example, the technical feature of Groups I and II and III of delaying progression of prostatic tumor cells to an androgen independent state is not a feature of any of the methods of Groups IV and V and VI. Further, the technical feature of inducing increased chemo- or radiation sensitivity of Groups IV and V and VI is not present in any of the methods of Group I or II or III.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant was contacted by telephone to confirm that the election filed 10-30-2003 would be maintained in this modified restriction, however, no confirmation could be obtained, so a new written restriction has been prepared. If applicant would like to confirm the election by telephone, please contact the examiner at the number listed below.

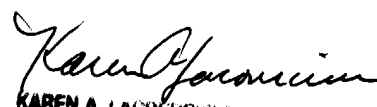
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
January 20, 2004


KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER